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May 7, 2025

VIA ECF

Honorable Ann M. Donnelly
United States District Court, Eastern District of New York
225 Cadman Plaza East, Court Room 4GN
Brooklyn, New York 11201

Re: *U.S. ex rel. Michael Olymbios, M.D. v. CareDx, Inc., et al.*, No. 1:21-cv-00774

Dear Judge Donnelly:

Plaintiff-relator Michael Olymbios, M.D. (“Relator”) respectfully submits this letter in response to the request for a pre-motion conference (ECF 62) that defendants CareDx, Inc., Peter Maag, Reginald Seeto, Shamik Dholakia, and Sasha King (collectively “Defendants”) submitted concerning their motion(s) to dismiss the claims Relator has asserted to hold his former employer and certain executives accountable for the fraud they perpetrated on the Medicare program by paying doctors a multitude of kickbacks to obtain tens of thousands of orders for CareDx tests.

I. DEFENDANTS’ MOTION(S) TO DISMISS SHOULD BE LIMITED TO THE GROUNDS SPECIFIED IN THEIR PRE-MOTION CONFERENCE REQUEST

Defendants appear to view this conference as a meaningless exercise. They had more than a month to determine whether the Amended Complaint contains any pleading deficiencies or whether they have any defenses warranting dismissal under Fed. R. Civ. P. 12(b). Yet Defendants state that they have not fully decided what challenges they will assert in their motion(s) to dismiss and proceed as though they have no obligation to disclose in their request for a pre-motion conference all grounds upon which they will seek dismissal. *See* Def.’s Request (ECF 62) at 2 n.3. Making matters worse, Defendants avoid informing Relator and the Court as to how many motions they will file – one omnibus motion or multiple individual motions. *See id.* at 3 n.5. By being evasive, Defendants are not making a good faith effort to narrow the issues before filing their motion(s), rendering this process a trivial exercise. Defendants should be precluded from asserting any challenges in their motion(s) that are not included in their request for a pre-motion conference.

II. THE ATTACKS ON THE AMENDED COMPLAINT OUTLINED IN THE REQUEST FOR A PRE-MOTION CONFERENCE LACK MERIT

A. The Amended Complaint pleads causes of action for violations of the AKS and FCA

The False Claims Act (“FCA”) imposes liability on any person who “knowingly presents ... a false or fraudulent claim for payment or approval; [or] knowingly makes ... a false record or

statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(A)-(B). The Anti-Kickback Statute (“AKS”) makes it illegal to “knowingly and willfully ... pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to ... order ... any ... service[] or item for which payment may be made in whole or in part under a Federal health care program[.]” 42 U.S.C. § 1320a-7b(b)(2)(B). There are two pathways to establishing FCA liability for violations of the AKS: (1) *the false certification pathway* – a person falsely represents compliance with the material requirement that there be no AKS violation in connection with the claim for payment submitted to Medicare; and (2) *the AKS pathway* – under 42 U.S.C. § 1320a-7b(g), “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” *See, e.g., U.S. v. Regeneron Pharm., Inc.*, 128 F.4th 324, 332-35 (1st Cir. Feb. 18, 2025). Relator is pursuing relief on behalf of the Medicare program under both FCA liability pathways.

The Amended Complaint contains detailed allegations concerning Defendants’ willful provision of kickbacks, including travel, expensive dinners, hotels, fees for sham speaker programs and advisory boards, and payments disguised as research grants, to induce doctors to order AlloSure tests. *See, e.g., Am. Compl.* (ECF 42-1; 51) at ¶¶ 2, 27, 35, 49, 59, 69, 73-74, 79, 86, 97, 101. Contrary to Defendants’ generalized assertions, Relator alleges facts that create a plausible inference that the alleged kickbacks had significant value and were provided for the purpose of inducing doctors to order tests for Medicare patients. *See id.* at ¶¶ 35, 49, 61, 63, 68, 70, 73, 76, 83, 95, 97, 101-102, 107.

Similarly, Defendants’ contention that Relator does not allege a plausible causal connection between the remuneration and the recipient physicians’ AlloSure orders is false. Relator identifies several illustrative examples of doctors and medical centers who ordered AlloSure tests after receiving Defendants’ kickbacks and alleges that CareDx subsequently billed and received payment from Medicare for the tainted tests. *See id.* at ¶¶ 65, 68, 70, 80-81, 83, 84, 94-95, 105, 106, 108, 109. Relator also explains how Defendants tracked the impact their kickbacks had on AlloSure sales. *See id.* at ¶¶ 2, 67, 78, 83, 97, 107.

Defendants’ unsupported allegation that Medicare knew CareDx was offering free at-home phlebotomy services for AlloSure tests, as well as for non-CareDx tests, to induce physicians to order AlloSure tests is a defense founded upon allegations that are the very opposite of what Relator alleges. This factual dispute cannot be decided at the motion to dismiss stage.

B. The Amended Complaint satisfies Rule 9(b)

A complaint satisfies Rule 9(b) if it makes “plausible allegations ... that lead to a strong inference that specific claims were indeed submitted.” *See U.S. ex rel. Chorchos v. Am. Med. Response, Inc.*, 865 F.3d 71, 93 (2d Cir. 2017). Relator alleges CareDx provided kickbacks to numerous physicians to induce AlloSure orders, identifying several of the doctors. *See Am. Compl.* at ¶¶ 80-81, 94-95, 108. And, as Relator alleges, CareDx acknowledges that most patients who received AlloSure tests were Medicare patients. *See id.* at ¶¶ 45, 55-56, 58. As the billing party, CareDx possesses the details of all the bills it submitted to Medicare falsely certifying compliance with the AKS.

In accordance with Rule 9(b), Relator also sets forth the who, what, when, and where of the AKS and FCA violations. *See, e.g., U.S. ex rel. Gordon v. Shiel Med. Lab'y*, No. 16-cv-1090, 2025 WL 949432, at *14 (E.D.N.Y. Mar. 29, 2025). Relator details illustrative examples of the sham advisory board meetings and speaker programs, dinners, payments disguised as grants, and free services that constitute kickbacks, and likewise specifies physicians who received the alleged kickbacks, CareDx employees present at the events, approximate dates, and locations. *See, e.g., Am. Compl.* at ¶¶ 74, 80-82, 86, 94-96, 105, 108.

Defendants incorrectly argue Relator must plead an example of a bill that Medicare denied. To the contrary, courts recognize that before discovery and formal adjudication, a relator's allegations are just that – allegations. A general assertion that the Government is aware of a lawsuit but continues to pay the defendant's bills cannot negate plausible materiality allegations. *See U.S. ex rel. Foreman v. AECOM*, 19 F.4th 85, 115 (2d Cir. 2021). Relator plausibly alleges materiality, and it is beyond dispute that AKS compliance is material to Medicare payment decisions. *See, e.g., U.S. ex rel. Arnstein v. Teva Pharm. USA, Inc.*, 2019 WL 1245656, at *28 (S.D.N.Y. Feb. 27, 2019).

III. DEFENDANTS' ACCUSATIONS DO NOT BELONG IN A MOTION TO DISMISS

In an effort to distract from the allegations and illegal conduct at issue, Defendants continue trying to vilify the person reporting their fraud, including making unfounded claims regarding a purported breach of the seal. The accusation Relator shared his complaint with other physicians while the case was under seal is false. In addition to being factually baseless, were Defendants to proceed with moving to dismiss on this ground, the contention would be procedurally improper. This is a defense clearly premised on allegations that are entirely outside of Relator's pleading. A motion to dismiss is not the place for Defendants to lodge accusations that have no mooring in the complaint or any incorporated documents.

IV. RELATOR REQUESTS A MORE EQUITABLE BRIEFING SCHEDULE THAN THE SCHEDULE DEFENDANTS PROPOSE

In their proposed schedule, Defendants afford themselves 90 days from service of the Amended Complaint to file their motion(s) to dismiss. And Defendants give themselves 29 days to later submit reply briefing. While giving themselves generous time to prepare their motion(s) and briefing, they propose that Relator have much less time to respond to their motion(s) – however many that may be (Defendants have kept the Court and Relator in the dark as to how many motions will be filed). Relator requests a fairer and less lopsided schedule requiring that (i) Defendants file their motion(s) within seven days of the Court's disposition of the request for a pre-motion conference, and (ii) Relator file his opposition(s) within 60 days of the motion(s).

Respectfully,

/s/ Gary L. Azorsky

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